

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

ERIC ANTHONY NEPUTE,
individually, and as
Owner of Quickwork LLC; and

Case No.: 4:21-cv-00437-RLW

**MEMORANDUM IN OPPOSITION
TO PLAINTIFF'S MOTION TO
EXCLUDE DEFENDANTS'
EXPERTS**

Dr. Parks and Dr. Nepute are well qualified by their education, training, and experience to offer their opinions. Their backgrounds easily qualify them to identify and analyze the relevant scientific evidence—the skill Plaintiff concedes as “essential”—and Plaintiff’s argument that only medical doctors are members of the relevant community is simply contrary to law. Plaintiff’s attack on Dr. Parks’s and Dr. Nepute’s methodology is conclusory, unfounded, and without support. Drs. Parks and Nepute connect the science of the underlying biological mechanisms by which vitamin D and zinc improve the immune system’s anti-viral response to studies demonstrating beneficial patient outcomes. Plaintiff’s contention that only randomized controlled trials (“RCTs”) constitute relevant scientific evidence is in direct conflict with recent Eighth Circuit precedent as well as the FTC’s own guidelines concerning the marketing of dietary supplements. Moreover, both experts explained why they discounted Plaintiff’s RCTs. Finally, Plaintiff seeks to bar all experts from offering testimony as to “how reasonable consumers would interpret [Dr.] Nepute’s statements.” Pl.’s Mem. at 9. No defense expert offers that opinion. The defense experts merely stated that they could not locate instances of Defendants’ alleged misstatements as characterized by the Complaint; Plaintiff’s own expert was also unable to do so.

Plaintiff’s attacks fall far short of showing the opinions are so “fundamentally unsupported” that they “offer no assistance to the jury.” Plaintiff’s attacks are proper grounds for cross-examination, not exclusion, and Plaintiff’s motion should be denied as set forth below.

ARGUMENT

FRE 702 governs the admissibility of expert testimony. *See Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006); *see generally Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). While the purpose of *Daubert* is to ensure the reliability of expert testimony, a “review of the caselaw after *Daubert* shows that the rejection of expert testimony is

the exception rather than the rule.” Fed. R. Evid. 702 advisory committee note. Indeed, as the Eighth Circuit recently held in reversing the exclusion of a medical causation expert, an expert’s opinion may only be excluded “if it is so fundamentally unsupported by its factual basis that it can offer no assistance to the jury.” *In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, 9 F.4th 768, 778 (8th Cir. 2021) (emphasis added). The Eighth Circuit further instructed that “gaps in an expert witness’s knowledge go to weight, not admissibility.” *Id.* “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means” of addressing “shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

I. Drs. Parks and Nepute Are Qualified to Provide Expert Testimony.

“Rule 702 only requires that an expert possess ‘knowledge, skill, experience, training, or education’ sufficient to ‘assist’ the trier of fact, which is ‘satisfied where expert testimony advances the trier of fact’s understanding to any degree.’” *Robinson v.* 447 at 1100 (emphasis added). The relevant inquiry is not whether the expert practices in a particular field, possesses particular titles or credentials, or has the identical specialty of the opposing expert, but instead whether the putative expert’s background, taken as a whole, demonstrates the expert is sufficiently qualified to provide the proffered opinions. *See id.*

A. Dr. Christina Parks holds a Ph.D. in cellular and molecular biology and is well qualified to provide her opinions.

Dr. Parks will offer testimony regarding the scientific substantiation for Defendants’ alleged statements concerning zinc, including zinc’s (1) role and benefit with respect to immune system function; (2) impact on the immune system’s antiviral response, including inhibiting viral replication; (3) ability to reduce the likelihood of developing COVID-19 symptomology; and (4) potential to improve outcomes in COVID-19 patients. *See Pl.’s Ex. 3.* at 5-12. Dr. Parks will assist

the trier of fact by explaining the underlying biological processes at issue, zinc's impact on those processes, and the research related to zinc and the immune system's anti-viral response, including specifically with respect to COVID-19, SARS-CoV-2, and similar viruses. *Id.* at 5-12, Ex. A.

Dr. Parks is qualified through her education, training, and experience to provide this testimony. She received a B.S. degree from the University of Wisconsin with a double major in Biochemistry and Molecular Biology. *See* Pl.'s Ex. 3. She earned her Ph.D. in Cellular and Molecular Biology from the University of Michigan after an arduous 12 year program. *Id.*

Dr. Parks's doctoral work required her to possess a deep and broad understanding of the immune system. *See* Ex B. 12:1-13:25. The focus of her doctoral work was cytokine signaling. *Id.* Cytokines are molecules the immune system uses to signal, including on how to respond to pathogens. *See id.* Cytokines are of particular relevance in this case as "cytokine storms," a condition in which an overactive immune system attacks healthy cells causing serious inflammation, is a leading cause of death in COVID-19 patients. *Id.* 138:21-143:24. Her research also included the inhibition of Interleukin-6, which is one of the most inflammatory cytokines. *Id.* 16:25-19:3. An Interleukin-6 inhibitor is currently used in the treatment of COVID-19. *Id.*

Dr. Parks is a scientific and medical educator. *See* Pl. Ex 6. She has spent her professional life in biological science, first as a researcher and more recently as an educator teaching college-level biology to high schoolers. *See id.* Through her business, New Health Paradigms, Dr. Parks is retained to interpret and explain complex scientific processes and interaction of cells. Ex. B 38:7-11, 20-23. Plaintiff's criticism that Dr. Parks' tenure as an educator in the relevant field of study is as offensive as it is misplaced. Pl.'s Mem. at 6.

Plaintiff concedes that Dr. Parks' educational background is relevant,¹ yet argues she is not qualified because she is not a medical doctor. Pl.'s Mem. at 6. Plaintiff does not cite any legal authority for the proposition that the lack of a medical degree is disqualifying. *See generally*, Pl.'s Mem. Courts have repeatedly held that the FRE 702 standard is not focused upon particular titles. *Hogland v. Town & Country Grocer of Fredericktown Missouri, Inc.*, 2015 WL 3843674, at *29 (holding a certified life care planner with a Ph.D. in rehabilitation was qualified to provide an expert vocational analysis despite not being a medical doctor trained in neurology). Nor must the expert have education or experience in a specific field at issue. *See In re Zurn Pex Plumbing Prod. Liab. Litig.*, 267 F.R.D. 549, 557 (D. Minn. 2010), *aff'd* 644 F.3d 604 (8th Cir. 2011) (holding statistics expert was qualified to analyze plumbing product failure rate data despite inexperience with products and not being a metallurgist or chemist); *Union Cnty., Iowa v. Piper Jaffray & Co.*, 2010 WL 11679204, at *3 (S.D. Iowa Dec. 5, 2010) (permitting expert without experience in municipal finance, the specific field at issue, to testify given education and experience in general finance). In particular, courts have repeatedly held that experts need not possess a particular degree or have conducted their own clinical trials in order to reliably opine on clinical studies. *See e.g.*, *Obesity Rsch. Inst., LLC v. Fiber Rsch. Int'l, LLC*, No. 15-CV-595-BAS(MDD), 2017 WL 1166307, at *2, 4 (S.D. Cal. Mar. 29, 2017) (discussed below); *Lewert v. Boiron, Inc.*, 212 F. Supp. 3d 917, 925-28 (C.D. Cal. 2016), *aff'd*, 742 F. App'x 282 (9th Cir. 2018) (permitting an expert to testify as to whether clinical trials supported drug efficacy claims despite not being a practicing physician and never running a clinical trial); *see also In re: Lipitor (Atorvastatin*

¹ Plaintiff objects to her earning her degree in 1999. Pl.'s Mem. at 6 ("While Dr. Parks has a Ph.D. in cellular and molecular biology, she earned her degree in 1999."). Plaintiff does not explain why that matters, nor is it even clear if Plaintiff's position is that 1999 was too recent or too long ago. Suffice to say it is immaterial to her qualifications and, coincidentally, Plaintiff's expert earned his medical degree in the same year. *See* Ex. C.

Calcium) *Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 2:14-MN-02502-RMG, 2016 WL 2940784, at *3 (D.S.C. May 6, 2016).

In *Obesity Research*, Plaintiff retained an expert witness to analyze the results of various peer-reviewed studies and opine on whether certain claims about drug efficacy were adequately substantiated in scientific evidence. 2017 WL 1166307, at *2. The expert held a Ph.D. in biomedical engineering and had previously worked in the analysis of biological molecules. *Id.* at *4. Defendant sought to exclude the expert's testimony, arguing that she lacked qualifications to opine on the relevant studies because she was not a medical doctor and had never run a clinical trial. *Id.* The court denied defendant's motion, holding that the expert's lack of a medical degree and lack of experience running clinical trials did not render her unqualified given her underlying education and experience. *Id.* Any remaining dispute regarding expert qualifications was a matter for cross-examination and did not justify exclusion of the expert's testimony. *Id.*

As in *Obesity Research*, Dr. Parks's lack of a medical degree is immaterial if she possesses other relevant and sufficient education, training, or experience. She unquestionably does as she holds a doctorate in cellular and molecular biology—a field highly and directly relevant to her opinions. She has a deep understanding of the immune system and her doctoral research focused on cytokines, which are particularly relevant to this case as Defendants are alleged to have made misstatements about their functioning and role in the development of cytokine storms. Ex. B 13:13-14:6. Additionally, she has extensive education and knowledge of cellular and viral replication—which is highly relevant given the claims that Defendants misrepresented zinc's ability to inhibit viral replication. *Id.* 11:23-25; 41:25-42:2.

Plaintiff additionally contends that Dr. Parks is not an expert in zinc. Pl.'s Mem. at 7. The relevant inquiry is whether Dr. Parks (or the other experts) possess sufficient foundational

qualifications through the enumerated FRE 702 criteria to be able to opine on whether the scientific evidence supports the statements.² See *Lewert*, 212 F. Supp. 3d at 927-28. Plaintiff agrees, stating “[Dr. Parks’s] ability to correctly identify and analyze the relevant medical literature is essential[.]” but then states in conclusory fashion that she “lacks the training and experience” to do so. Pl.’s Mem. at 7 (emphasis added). Plaintiff fails to explain how or why a Ph.D. in cellular and molecular biology would be unable to review scientific (including medical) evidence. As Dr. Parks’ testified, because of her extensive education and training, as well as her professional experience, she can comprehend, analyze, evaluate, and critique the scientific evidence relevant to this case (e.g., *in vitro*, observational, and RCTs), including not only the methodologies and results of such studies, but also a thorough understanding of their inherent limitations and their respective benefits and drawbacks. Ex. B 14:2-16:10. It is clear Dr. Parks does possess this “essential” skill and Plaintiff has nothing but unsupported argument to the contrary. *Id.* 14:2-16:10; 67:10-70:1; 79:21-82:19.

B. Dr. Eric Nepute is qualified to provide opinions in connection with defending statements and providing scientific support for vitamin D and zinc.

Many of the alleged misstatements at issue in this case were either made directly by Dr. Nepute or were based on his scientific knowledge. Out of an abundance of caution, Defendants provided a “hybrid” disclosure pursuant to Rule 26(a)(2)(C) to forestall any argument by Plaintiff that it was prejudiced by a failure to disclose Dr. Nepute’s opinions and expertise. Whether he testifies as an expert or fact witness, Dr. Nepute is entitled to provide the scientific basis upon which he made the alleged misstatements.

Plaintiff’s singular argument for excluding Dr. Nepute is that “he lacks the relevant medical expertise.” Pl.’s Mem. at 7. But as already shown, holding the title of medical doctor is not a

² Plaintiff’s expert, Dr. Dubberke, conceded his expertise does not lie in either vitamin D or zinc, yet he readily opines on the scientific literature as to both. See Ex. D. at 62:13-63:10; 114:18-115:1.

necessary prerequisite for expert testimony in this case. Instead, as Plaintiff articulated regarding Dr. Parks, the question is whether Dr. Nepute is sufficiently qualified to correctly identify and analyze relevant scientific evidence. *Id.* Through his education, training and experience, Dr. Nepute unquestionably possesses the ability to testify as to the scientific evidence supporting his statements regarding the properties of vitamin D and zinc.

Dr. Nepute earned a Bachelor of Science degree from Millikin University with a double major in Sports Medicine and Athletic Training. *See* Ex. E. His undergraduate studies included coursework in advanced chemistry and statistics. *See* Ex. F 26:10-12; 37:13-40:6.

Dr. Nepute achieved his degree as a Doctor of Chiropractic in 2006 from Logan University. Ex. F 22:2-21. The first two years of chiropractic training is largely identical to a medical program. *Id.* 22:24-23:7. Coursework includes scientific study of physical diagnosis, physiology, anatomy, and immunology. *Id.* Dr. Nepute also received advanced coursework in nutrition, biochemistry, organic chemistry, and clinical applications. *Id.* 23:8-11. During his residency, Dr. Nepute performed a wide variety of work in a clinical setting, including virology where he saw a “tremendous” number of infectious disease patients, particularly with diseases of the respiratory tract. *Id.* 29:7-31:12.

Dr. Nepute has extensive post-doctorate training. Ex. E. This includes obtaining certification as a Doctor of Natural Medicine. Ex. F at 31:16-24. This course of study focused on the recognition of deficiencies and/or toxicities on a cellular level in the human body, and included coursework on symptomatology and cellular dysfunction. *Id.* 31:22-32:5. Dr. Nepute is also credentialed as a Certified Nutrition Specialist and holds a certification in a diplomat program in internal health, which required 400 hours of internal health education. *Id.* 40:7-10; 43:1-19. Coursework included blood work, physiology, pathophysiology, virology, epidemiological

studies, nutrition, and how organic chemical compounds affect the cellular function of the body. *Id.* 43:20-44:5.

Between Dr. Nepute's doctorate and post-doctorate work, he received over 2,600 hours of education in clinical nutrition, including coursework on vitamin D and zinc and their role in the proper functioning of the immune system and anti-viral response. *Id.* 32:6-10. This compares favorably to medical doctors who only receive six hours of nutritional training. *Id.* 32:6-7.

Furthermore, while at Logan University, Dr. Nepute received extensive education on Plaintiff's self-described "essential" skill of identifying and analyzing the relevant scientific evidence. *Id.* 26:15-28:18; *see also* 167:15-170:22. He completed a two-year course on research techniques and analysis which focused on issues such as proper methodologies, confounding factors, statistical analysis, conflict of interests, bias, and critical review. *Id.* 26:15-28:18.

Dr. Nepute is the sole owner of Nepute Wellness Center ("NWC"), which is a fully integrated functional wellness center. *Id.* 51:19-23. NWC offers comprehensive wellness services to its patients with four chiropractors, two medical doctors, and a nurse practitioner on staff, all supervised by Dr. Nepute. *Id.* 62:8-63:17; 64:5-23.³ Dr. Nepute sees patients for a broad spectrum of health services and his work includes developing nutritional and supplementation care plans involving vitamin D and/or zinc. *Id.* 65:21-67:17. He held admitting privileges at BJC, Mercy Hospital and St. Alexis Hospital. *Id.* 50:24-51:10.⁴

To ensure his patients receive the highest standard of care, and as continuing education, Dr. Nepute has reviewed over 300 studies on vitamin D and 82 studies on zinc, including with respect to RNA viruses, coronaviruses, and COVID-19. *Id.* 15:3-10; 209:20-21.⁵ This study,

³ Dr. Nepute also co-owns Genetics Molecular Lab, which conducts PCR and genetic testing. *Id.* 71:8-9.

⁴ Dr. Nepute relinquished those privileges when NWC began employing its own M.D.s. *Id.* 51:11-18.

⁵ Dr. Nepute has identified and produced dozens of studies and reference materials relating to vitamin D and zinc. *See* Pl. Ex. 5.

combined with his education and long history of patient nutritional care, qualify him to testify both to the benefits of vitamin D and zinc as well as the absence of adverse side-effects.

Dr. Nepute is a highly educated and experienced health professional with extensive training in matters related to study methodology and critique, and possesses substantive knowledge of nutrition, supplementation, virology, epidemiology, and related fields. Based on the foregoing, Dr. Nepute is highly qualified to opine as to the scientific evidence regarding vitamin D's and zinc's benefit to the immune response to viral respiratory infections generally, and Covid-19 specifically. Dr. Nepute will testify that vitamin D and zinc can: (1) strengthen the immune system; (2) reduce the risk of developing Covid-19 symptomology; and (3) improve outcomes for Covid-19 patients.

Plaintiff contends that because Dr. Nepute is not a physician and is not involved in drug development, he is excluded from the "relevant scientific community" and cannot provide expert testimony in this matter. Pl.'s Mem at 8. Plaintiffs provide no citation to support their argument that only physicians and research scientists can be qualified to reliably analyze clinical evidence or scientific studies. The flexible standard embraced by the courts in *Obesity Research*, *Lewert*, and *In re Lipitor* counsels otherwise. Dr. Nepute's extensive education and experience demonstrate his qualification to provide testimony on the scientific bases for Defendants' statements.

II. Plaintiff's Attack On Drs. Parks' And Nepute's Zinc Methodologies Is Unfounded, Conclusory, And Ultimately Meritless

Plaintiff criticizes Drs. Parks and Nepute for not giving sufficient weight to specific RCTs, arguing that the failure to do so limits Defendants' ability to make ultimate causal conclusions about the relationship between zinc, vitamin D, and viral infections including Covid-19. Pl.'s Mem. at 10-15. Plaintiff's argument is meritless for several reasons.

- A. There has been no finding that Defendants' statements require causal substantiation in the form of RCTs and any such determination is premature.

First, Plaintiff's argument puts the cart before the horse. There has been no ruling in this case as to whether any statements made by Defendants require proof of causation from a RCT, or whether an alternative form of substantiation is sufficient. The requisite level of substantiation is a core matter in dispute in this lawsuit and is a point of vigorous disagreement between the parties' experts. Plaintiff asks the Court to simply accept its expert's opinion and find that any contrary opinions are methodologically unsound.

Plaintiff argues at length that RCTs are the "gold standard" of study design. *See* Pl.'s Mem. at 11-12. Dr. Parks and Dr. Nepute dispute the notion that scientists do not view other study designs as reliable and competent scientific evidence. Defendants' experts will testify that the body of scientific evidence, including *in vitro* and observational studies, of vitamin D and zinc demonstrate their beneficial effect in anti-viral immune response (including, but not limited to, COVID-19) and support Defendants' statements. *See* Pl. Exs. 3, 5.

Plaintiff's "RCT-only" position is not only factually disputed, it is also belied both by the FTC's own guidance and by controlling caselaw. First, the FTC's "Advertising Guide to the Industry" regarding dietary supplements recognizes that the standard for competent and reliable scientific evidence is flexible, must take into account the relevant circumstances, and does not comprise a "fixed formula for the number or type of studies required." *See* Ex. G (FEDERAL TRADE COMMISSION, *Dietary Supplements: An Advertising Guide for Industry* at 9, April 2001).⁶

Second, courts have noted the distinction between the FTC standard applicable to dietary supplements (i.e., competent and reliable scientific evidence) from the FDA standard for drugs (i.e., randomized, placebo-controlled, double-blind clinical trials per 21 C.F.R. 314.126(b)). *See*

⁶ In determining whether supplement claims are supported by appropriate substantiation, the FTC's guidance counsels industry members to take into account "the cost/feasibility of developing substantiation" to ensure that "valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive."

Mullins v. Premier Nutritional Corp., 178 F. Supp. 3d 867 (N.D. Cal. 2016); *USA v. Bayer Corp.*, 2015 WL 5822595 (D.N.J. 2015); *see also FTC v. QT.*, 512 F.3d 858, 861 (7th Cir 2008) (“Nothing in the [FTC] Act, the foundation of this litigation, requires placebo-controlled, double blind studies.”); *Bair Hugger*, 9 F.4th at 779 (observational studies that show associations can be admissible to show causation if supported by appropriate scientific judgment).⁷ As discussed below, the Eighth Circuit’s decision last year in *Bair Hugger* eviscerates the legally erroneous contention that RCTs are the sole form of reliable and competent evidence.

Here, Plaintiff ignores its own guidance and controlling law. This position is particularly untenable given the specific facts of this case, which involve claims related to a worldwide pandemic caused by a novel coronavirus that, by its very definition, did not have any pre-existing research. The circumstances of the pandemic and the absence of a body of COVID-19 specific research augur in favor of a standard of solely RCT studies.⁸ Even if the medical community were the only relevant field (it is not), it has recognized the need to apply a less-stringent standard during the pandemic as thousands of medical doctors have recommended zinc and vitamin D supplementation without the benefit of the RCTs Plaintiff would require. Ex. F at 142:21-24.

B. The Eighth Circuit has definitively held that a causal relationship can be established by observational and other non-RCT studies

Second, Plaintiff is incorrect as a matter of law that RCTs are necessary to show causation. The Eighth Circuit addressed precisely this question in its 2021 *Bair Hugger* opinion. There, the Eighth Circuit held that it was not “unreliable for an expert to draw an inference of causation from

⁷ Plaintiff’s reliance on *Smith v. Bubak*, a medical malpractice case applying South Dakota law, is misplaced as the entire causation analysis relied on a state statute having no application whatsoever to this case. 643 F.3d 1137, 1140 (8th Cir. 2011).

⁸ *See* Ex. G at 8 (requiring that an appropriate measure of substantiation take into account “the cost/feasibility of developing substantiation” to ensure that “valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive.”).

an epidemiological [i.e., observational] study that disclaimed proving causation.” *Bair Hugger*, 9 F.4th at 779. To the contrary, the Eighth Circuit held observational studies “can be brought to bear on the issue of causation and can be very useful to answering that question.” *Id.* (internal quotations and citations omitted). If an expert “bridges” the causal gap, “a study disclaiming having proven causation may nevertheless support such a conclusion.” *Id.* at 779-80.

Drs. Parks and Nepute sufficiently bridge the gap between association and causation through analysis of both observational studies and *in vitro* studies. Contrary to Plaintiff’s characterizations, Dr. Parks had a very clear methodology. She applied her extensive education and training to the body of scientific evidence regarding zinc and its role in the proper functioning of the immune system. Her methodology included analyzing relevant *in vitro* studies demonstrating biological mechanisms by which zinc benefits the immune system. Pl. Ex. 3 at 6. These biological mechanisms are known through the study of other RNA and/or coronaviruses (COVID-19 is both). This includes *in vitro* studies showing zinc “prevents replication of SARS CoV-1 by inhibiting its viral RNA polymerase.” *Id.* at 9. Inhibiting viral replication results in lower viral loads, which in turn results in potentially lessened or no symptoms from viral infections, such as COVID-19. Ex. F at 152:14-153:19. Dr. Parks also relies upon *in vitro* and other studies establishing that zinc sufficiency is necessary to maintaining the immune system’s anti-inflammatory state, which can prevent inflammatory responses leading to “cytokine storms” and acute respiratory distress syndrome (“ARDS”) in COVID-19 patients. Pl. Ex. 3 at 12.

With an understanding of the biological mechanisms at play, Dr. Parks reviewed the scientific literature for evidence that these biological mechanisms identified in *in vitro* or other studies were resulting in improved patient outcomes. *Id.* at 6, 12-13. Dr. Parks testified that the observational studies confirmed that the biological mechanisms were having real-world benefits

to patient outcomes, including with respect to COVID-19. *Id.* at 13. As just one example, Dr. Parks relies upon a study published in the journal *Nutrients* that found a correlation between depressed zinc levels and increased risk of death from COVID-19. *Id.* Bolstering this finding, a converse correlation was found in patients who received zinc supplementation—that is, patients who did not receive zinc supplementation were more than seven times more likely to develop a symptomatic COVID-19 infection. *Id.*

Dr. Nepute performed a similar analysis with respect to both zinc and vitamin D.⁹ He reviewed over 400 vitamin D and zinc studies in reaching his opinions that form the scientific basis of the statements at issue in this case. Ex. F. at 138:17-144:15. This extensive body of research included in vitro studies demonstrating the biological mechanisms by which vitamin D and zinc improve the immune system’s antiviral response by, for example, inhibiting viral replication. See e.g., *id.* at 138:17-144:15, 152:14-153:19, 192:8-193:24. These mechanistic studies provide the biological bases to explain how vitamin D and zinc supplementation leads to the improvement in patient outcomes shown by the observational studies he also relied upon. *Id.* at 239:15-241:7, 321:11-325:21.

Drs. Parks’ and Nepute’s analysis is precisely the type of gap-bridging evidence that was deemed sufficient in *Bair Hugger*. *Id.* at 780-81 (finding that the epidemiological data was supported by expert analysis of studies showing plausible biological mechanisms by which the causation could occur). Indeed, Plaintiff’s expert engaged in the same methodology—reviewing the scientific evidence—except he rigidly ignored all non-RCT studies irrespective of their methodologies, quality, or findings. Ex. F Vol. I 74:14-76:20; Dubberke Rep. ¶¶ 29-32.

⁹ Dr. Nepute’s deposition is replete with examples of his analysis of *in vitro*, observational, meta, and RCTs, *i.e.*, the body of scientific evidence. See *id.* 135:18-138:8, 165:14-168:17, 169:8-171:22, 188:21-194:17, 196:4-201:10, 201:20-212:6.

The only methodological difference between the Drs. Park and Nepute and Plaintiff's expert is that Defendants' experts considered all the scientific evidence while Plaintiff's limited himself to only a small subset. In fact, both Drs. Parks and Nepute will testify to RCTs' inherent shortcomings, including (1) it would be unethical to withhold zinc from a patient who was known to be zinc deficient and (2) the extraordinary time and cost of RCTs can unnecessarily delay use of supplementation (which has no adverse side-effects) during a global pandemic caused by a novel virus. Ex. F at 165:14-186; Ex. B at 148:7-150:5.

Plaintiff pays lip service to *Bair Hugger* by stating “the methodological flaw in these expert opinions is *not* that the rely on observational and *in vitro* studies,” but spends most of its argument attacking Dr. Parks for supposedly “disregard[ing]” two RCTs cited by Dr. Dubberke. Pl.'s Mem. at 14-15. Dr. Parks did not “disregard” the RCTs. To the contrary, they are identified in her report in the materials relied upon. Ex. A at 11.

At her deposition, she explained why she gave the *Thomas* study less weight—it analyzed the administration of zinc and vitamin C to treat COVID patients after the onset of the infection as opposed to prophylactically. Ex. B. 182:8-184:23. As Dr. Parks repeatedly stated, zinc supplementation is more effective when undertaken prophylactically as opposed to a treatment after infection and symptomatology have occurred. *Id.* at 90:24-94:5; Pl. Ex. 3 at 5-6. 12-13.¹⁰

Dr. Parks explained precisely why she did not give greater weight to the RCT studies—Plaintiff simply does not like her explanation. Disagreement between the parties' experts is the classic “battle of the experts” that is properly resolved via cross-examination and it is not a basis for exclusion. *See Bair Hugger*, 9 F.4th at 778.¹¹ Plaintiff barely makes any argument as to Dr.

¹⁰ Plaintiffs do not even offer an argument as to the other study Defendants will not engage in speculation as to what point, if any, Plaintiff intended to make.

¹¹ For this same reason, Plaintiff's attempt to factually distinguish *Bair Hugger* on the grounds that the Eighth Circuit was not presented with any reliable RCT evidence is misplaced. *See* Pl.'s Mem. at 13, fn.6.

Nepute's methodology at all—citing to less than a page of deposition testimony. Pl.'s Mem. at 14. Plaintiff's conclusory argument as to Dr. Nepute is the result the brevity of counsel's questioning on the topic. Plaintiff has not raised any issue that would leave either expert's methodology bereft of support which would render their testimony inadmissible. *See id.*

III. None Of Defendants' Experts Are Offering Consumer Interpretation Testimony

Plaintiff's final criticism is that Dr. Parks and Dr. Holick are offering testimony as to "how reasonable consumers would interpret [Dr.] Nepute's statements." Pl.'s Mem. at 9. Neither expert offer such an opinion.

The two experts simply stated that they could not locate instances of Defendants' alleged misstatements as characterized by the Complaint. *See id.* at 9. As Plaintiff's brief concedes, Dr. Holick merely testified that he "was unable to correlate the Defendants' statements [regarding vitamin D and COVID-19] in the record [he] reviewed with the government's characterization of those statements." *Id.* Indeed, Plaintiff's own expert, Dr. Erik Dubberke was unable to identify instances of Defendants' alleged misstatements as characterized by Plaintiff during his testimony. *See Ex. H* at 155:7-15; 200:23-201:10; 224:13-225:12.

Neither expert will opine as to what a reasonable consumer would have understood from any of Defendants' statement, nor the net impression to consumers of any particular statement. At most, they will simply state that they have not seen the alleged misstatements in the record. Plaintiff is free to cross-examine the experts on this point if it so wishes.

CONCLUSION

For the foregoing reasons, Plaintiff's motion must be denied.

Dr. Parks's testimony explains why Plaintiff's RCT evidence is fundamentally flawed and is otherwise inapplicable to the specific questions of zinc at issue here. Moreover, even if Plaintiff's statement were factually true, there is nothing in the Eighth Circuit's decision suggests that its holding was reached only because of the absence of RCT evidence.

Dated: September 23, 2022

Respectfully submitted,

McCARTHY, LEONARD &
KAEMMERER, L.C.

THOMPSON COBURN LLP

By: /s/ S. Jay Dobbs
Brian E. McGovern, #34677
S. Jay Dobbs, #40859
Bryan M. Kaemmerer, #52998
825 Maryville Centre Drive, Ste. 300
St. Louis, Missouri 63017
bmcgovern@mlklaw.com
jdobbs@mlklaw.com
bkaemmerer@mlklaw.com

By: /s/ Jan Paul Miller
Jan Paul Miller #58112
Mark Mattingly #56536
One U.S. Bank Plaza
St. Louis, Missouri 63101
(314)552-6000
jmiller@thompsoncoburn.com
mmattingly@thompsoncoburn.com

Attorneys for Eric Anthony Nepute

Attorneys for Quickwork, LLC

CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2022, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system to all counsel of record.

/s/ S. Jay Dobbs